

The attached excerpts from EPA's Water Quality Standards Handbook include pages referenced in EPA's February 2, 2015 decision documents.



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Water Quality Standards Handbook

NEW IN 2014: UPDATED CHAPTERS

The *Water Quality Standards Handbook* is a compilation of the EPA's water quality standards (WQS) program guidance including recommendations for states, authorized tribes, and territories in reviewing, revising, and implementing WQS. The guidance in this Handbook supports the EPA's WQS regulations at [40 CFR Part 131](#).

The *Water Quality Standards Handbook* was first issued in 1983 and provided a compilation of the EPA's WQS guidance to-date.

In 1994, *The Water Quality Standards Handbook: Second Edition* was issued and retained all of the guidance in the 1983 Handbook unless such guidance was specifically revised in subsequent years. The 1994 Handbook also contained new EPA guidance that was developed between 1983 and 1994.

In 2007 and 2012, the EPA updated the online version of the Handbook to incorporate minor enhancements including links to additional information and resources that the EPA developed subsequent to 1994. However, the text of the chapters did not change from the 1994 Handbook.

In 2014, the EPA updated certain chapters of the online version of the Handbook to reflect guidance that the EPA has already publicly articulated in other forms of documentation and streamlined the text to make the document more user friendly.

The 2014 update also utilizes current technology that allows the Handbook to serve as an online "living document." As such, the EPA will update the online Handbook as new guidance becomes available and will not publish a new printed edition.

For any questions related to the guidance in this Handbook, please [contact us](#). Copies of any referenced document can be obtained by clicking on the hyperlink or visiting the [Policy and Guidance: Reference Library](#) webpage.

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Water Quality Standards Handbook - Chapter 5: General Policies (40 CFR 131.13)

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Introduction

As specified in [40 CFR 131.13](#), states and authorized tribes may, at their discretion, adopt certain policies into their water quality standards (WQS) that generally affect how their WQS are applied or implemented. Examples of such general policies include those affecting mixing zones, critical low flows, and WQS variances.¹ As the regulation indicates, states and tribes are not required to adopt general policies. However, if a state or tribe chooses to adopt a general policy, such policies are subject to EPA review and approval or disapproval under Section 303(c) of the [Clean Water Act \(CWA\)](#) if they constitute new or revised WQS (see [Chapter 1](#) of this Handbook). This chapter provides an overview of three types of general WQS policies. In particular, Section 5.1 of this chapter discusses mixing zones, Section 5.2 discusses critical low flows, and Section 5.3 discusses variances.

5.1 Mixing Zones

A mixing zone is a limited area or volume of water where initial dilution of a discharge takes place and where certain numeric water quality criteria may be exceeded. The [CWA](#) does not require that all criteria be met at the exact point where pollutants are discharged into a receiving water prior to the mixing of such pollutants with the receiving water. Sometimes it is possible to expose aquatic organisms to a pollutant concentration above a criterion for a short duration within a limited, clearly defined area of a waterbody while still maintaining the designated use of the waterbody as a whole. Where this is the case, a state or authorized tribe may find it appropriate to allow ambient concentrations of a pollutant above the criterion in small areas near point-source outfalls (i.e., mixing zones).

Mixing zones do not constitute new state or tribal criteria or changes to the state- or tribe-adopted and EPA-approved criteria. Therefore, the narrative and/or numeric criteria for the waterbody are still the applicable criteria within the boundaries of the mixing zone. A mixing zone simply authorizes an applicable criterion to be exceeded within a defined area of the waterbody while still protecting the designated use of the waterbody as a whole. Since 1983, the guidance in this Handbook has described mixing zones as areas where criteria may be exceeded rather than areas where criteria do not apply.

By authorizing a mixing zone, states and tribes allow some portion of the waterbody to mix with and dilute particular wastewater discharges before evaluating whether the waterbody as a whole is meeting its criteria. In addition to the WQS regulation at [40 CFR 131.13](#) described above, the use of dilution is supported by the National Pollutant Discharge Elimination System (NPDES) permitting regulation at [40 CFR 122.44\(d\)\(1\)\(ii\)](#), which requires the permitting authority to consider, where appropriate, "the dilution of the effluent in the receiving water" when determining whether a discharge causes, has the reasonable potential to cause, or contributes to an instream excursion above a criterion. Depending on the state or tribal WQS and implementation policies, a consideration of dilution could be expressed in the form of a dilution allowance or a mixing zone. A dilution allowance typically is expressed as the flow or portion of the flow of a river or stream and is typically applied in flowing waters where rapid and complete mixing occurs. A mixing zone is typically applied in any waterbody type in which incomplete mixing occurs. For more information, see Chapter 6 of the [NPDES Permit Writers' Manual \(2010\)](#).

While mixing zones serve to dilute concentrations of pollutants in effluent discharges, they also allow increases in the mass loading of the pollutant to the waterbody (more so than would occur if no mixing zone were allowed). Therefore, if not applied appropriately, a mixing zone could adversely affect mobile species passing through the mixing zone as well as less mobile species (e.g., benthic communities) in the immediate vicinity of the discharge. Because of these and other factors, mixing zones should be applied carefully so that they do not result in impairment of the designated use of the waterbody as a whole or impede progress toward the CWA goals of restoring and maintaining the physical, chemical, and biological integrity of the Nation's waters. Keeping this in mind, a state or tribe has the discretion to choose whether to authorize mixing zones and adopt a mixing zone policy. However, as described below, if a state or tribe chooses to adopt a mixing zone policy, such a policy is generally considered a new or revised WQS that must be adopted into state or tribal law and approved by the EPA before it is effective for CWA purposes.

An important note is that "mixing zone" is used in multiple ways. A *mixing zone policy* is a legally binding state or tribal policy that is adopted into WQS and describes the general characteristics of and requirements associated with mixing zones without taking into account site-specific information. The EPA generally views such mixing zone policies as constituting new or revised WQS that require EPA review and approval or disapproval under Section 303(c) of the CWA. Consistent with the four-part test described in [What is a New or Revised Water Quality Standard Under CWA Section 303\(c\)? Frequently Asked Questions \(2012\)](#) and [Chapter 1](#) of this Handbook, a state or tribal mixing zone policy is a legally binding provision that is adopted into state or tribal law (part one), and it addresses the criteria component of WQS (part two). Additionally, a mixing zone policy expresses a desired condition in the waterbody to allow flexibility in meeting the applicable criteria within certain areas of the waterbody (part three), and if it is a new provision or revises an existing policy (part four), it clearly meets the requirements to be a new or revised WQS.

On the other hand, an *individual, site-specific mixing zone* is authorized for a particular point-source discharge in accordance with a state or tribal mixing zone policy and accounts for the site-specific characteristics of a particular discharge and receiving water. An individual mixing zone is defined and implemented through the NPDES permitting process. The EPA does not view individual mixing zones as constituting new or revised WQS requiring EPA review under Section 303(c). Like a mixing zone policy, an

individual mixing zone is a legally binding provision that is established pursuant to state or tribal law (part one), and it addresses the criteria component of WQS (part two). However, unlike a mixing zone policy, an individual mixing zone does not express or establish a desired condition in the waterbody (part three). Instead, the individual mixing zone is used to establish appropriate water quality-based effluent limits (WQBELs) for a specific discharger's NPDES permit. An individual mixing zone also does not establish a new provision or revise an existing provision (part four). Rather, it implements a WQS (i.e., the state or tribal mixing zone policy) for a specific discharger using site-specific information.

Additionally, any time an effluent is discharged into a receiving water, there will be a zone of *actual or physical mixing* in which the discharge and receiving water naturally mix regardless of whether a mixing zone, in the regulatory sense, has been authorized. Such actual mixing is described using field studies and a water quality model and is used in establishing an individual, site-specific mixing zone for a particular discharge.

The authorization of mixing zones under incompletely mixed discharge and receiving water situations pre-dates the CWA. The EPA's current mixing zone guidance, contained in this Handbook, the *Technical Support Document for Water Quality-based Toxics Control (TSD)* (1991), and the *NPDES Permit Writers' Manual* (2010), evolved from previous guidance from the EPA and its predecessor agencies on the use of mixing zones as a regulatory tool to address the incomplete mixing of wastewater discharges in receiving waters. This Handbook describes the EPA's recommendations for state and tribal mixing zone policies. The other two documents listed above describe the technical and permitting aspects of defining individual, site-specific mixing zones for point-source discharges during the NPDES permitting process. Additional information on mixing zones can also be found in the EPA's *Compilation of EPA Mixing Zone Documents* (2006) and *Advanced Notice of Proposed Rulemaking for Water Quality Standards* (1998).

5.1.1 Recommended Contents of State and Tribal Mixing Zone Policies

The EPA recommends that states and authorized tribes adopt, at a minimum, a definitive statement into their WQS specifying whether the state or tribe intends to authorize mixing zones. Consistent with the discussion above, where a mixing zone is authorized, water quality criteria are met at the edge of the mixing zone during critical low-flow conditions (which are described in Section 5.2 of this chapter) so that the designated use of the waterbody as a whole is protected. If a state or tribe chooses to adopt a mixing zone policy, such a policy should ensure the following:

- Mixing zones do not impair the designated use of the waterbody as a whole.
- Pollutant concentrations within the mixing zone are not lethal to organisms passing through the mixing zone.²
- Pollutant concentrations within the mixing zone do not cause significant human health risks considering likely pathways of exposure.
- Mixing zones do not endanger critical areas such as breeding or spawning grounds, habitat for threatened or endangered species, areas with sensitive biota, shellfish beds, fisheries, drinking water intakes and sources, or recreational areas.

Because pollutant concentrations may exceed numeric criteria within mixing zones, these elevated concentrations could adversely affect the productivity of the waterbody and have unanticipated ecological consequences. Therefore, the EPA recommends that the use of mixing zones in the development of WQBELs in NPDES permits be carefully evaluated and appropriately limited on a case-by-case basis in light of the overarching requirement to protect the designated use of the waterbody as a whole pursuant to [40 CFR 131.10](#).

Due to potential additive or synergistic effects of certain pollutants that could result in the designated use of the waterbody as a whole not being protected, state and tribal mixing zone policies should specify, and permitting authorities should ensure, that mixing zones do not overlap. Additionally, the EPA recommends that permitting authorities evaluate the cumulative effects of multiple mixing zones within the same waterbody. The EPA has developed a holistic approach to determine whether a mixing zone is appropriate based on such cumulative effects considering all of the impacts to the designated uses of the waterbody (see [Allocated Impact Zones for Areas of Non-Compliance](#) (1995)). If the total area affected by elevated concentrations within all mixing zones combined is small compared to the total area of the waterbody in which the mixing zones are located, then mixing zones are likely to have little effect on the designated use of the waterbody as a whole, provided that they do not impinge on unique or critical habitats. As understanding of pollutant impacts on ecological systems evolves, states and tribes may find specific cases in which no mixing zone is appropriate.

States and tribes that choose to adopt mixing zone policies should describe the general procedures for defining and implementing mixing zones in terms of location, maximum size, shape, outfall design, and in zone water quality, at a minimum. Such policies should be sufficiently detailed to support regulatory actions, issuance of permits, and determination of best management practices for nonpoint sources.

The EPA recommends that specific characteristics of an individual mixing zone for a specific discharger be defined on a case by case basis using the state or tribal mixing zone policy. This site-specific assessment would ideally take into consideration the physical, chemical, and biological characteristics of the discharge (including the type of pollutant discharged) and receiving waterbody; the life history and behavior of organisms in the receiving waterbody; and the designated uses of the waterbody.

Location

States and authorized tribes should restrict the potential locations of mixing zones as a way to protect stationary benthic organisms and human health from the potential adverse effects of elevated pollutant levels. In addition, states and tribes should prohibit mixing zones where they may endanger biologically important and other critical areas that the state, tribe, or federal government has identified. These include breeding and spawning grounds, habitat for threatened or endangered species, areas with sensitive biota, shellfish beds, fisheries, drinking water intakes and sources, and recreational areas.

Pollutant concentrations above the chronic aquatic life water quality criterion may prevent sensitive taxa from living and reproducing successfully within the mixing zone. In this regard, benthic and territorial organisms may be of greatest concern in protecting aquatic life within a mixing zone. The higher the pollutant concentrations occurring within the mixing zone, the more taxa are likely to be adversely affected, thereby affecting the structure and function of the ecological community and, potentially, the designated use of the waterbody as a whole.

For protection of human health, states and tribes should restrict mixing zones such that they do not result in significant human health risks when evaluated using reasonable assumptions about exposure pathways. For example, where drinking water contaminants are a concern, the mixing zones should not encroach on drinking water intakes and sources. Where fish tissue residues are a concern (either because of measured or predicted residues), mixing zones should not result in significant human health risks to average and sensitive subpopulations of consumers of fish and shellfish after considering exposure duration of the affected aquatic organisms in the mixing zone and the patterns of fisheries use in the area. Where waters are designated for primary contact recreation, mixing zones for bacteria should not result in significant human health risks to people recreating in such waters. In all cases, it is critical that the designated use of the waterbody as a whole is protected.

Size

In order to protect the designated uses of the waterbody as a whole, pollutant concentrations within any mixing zone should not be lethal to mobile, migrating, and drifting organisms in the waterbody or cause significant human health risks considering likely pathways of exposure. One means of achieving these objectives is to limit the size of the mixing zone.

Most states and authorized tribes allow mixing zones as a matter of policy but also specify general spatial dimensions that limit their size. States and tribes have developed various methods of defining the maximum allowable size of mixing zones for various types of waters. State and tribal policies dealing with streams and rivers often limit mixing zone widths, cross sectional areas, and/or flow volumes and allow lengths to be determined on a case by case basis. For lakes, estuaries, and coastal waters, dimensions are usually specified by surface area, width, cross sectional area, and/or volume. The EPA recommends that states and tribes use methods that result in quantitative measures sufficient for permitting authorities to develop WQBELs in a transparent and straightforward manner.

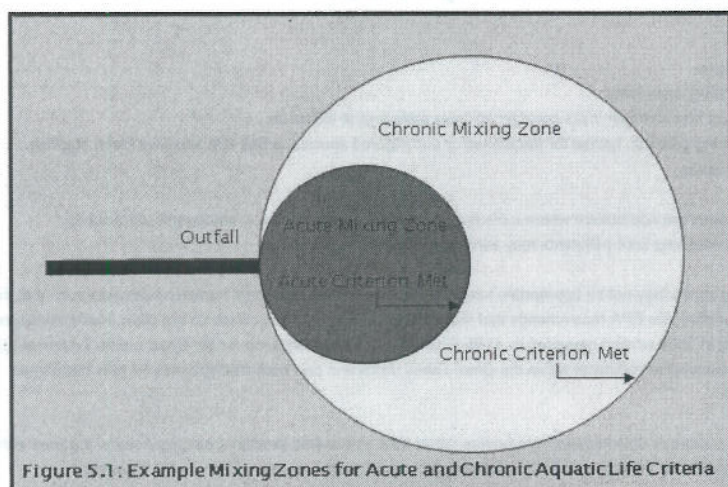
If a mixing zone is authorized for a specific discharge, the permitting authority then defines the actual size of an individual, site-specific mixing zone for the specific discharge on a case-by-case basis using the general size restrictions in the state or tribal mixing zone policy. The area or volume of an individual mixing zone or group of mixing zones should be as small as practicable so that it does not interfere with the designated uses or with the established community of aquatic life in the segment for which the uses are designated.

In general, where a state or tribe has both acute and chronic aquatic life water quality criteria as well as human health criteria for the same pollutant, states and tribes may establish independent mixing zone size specifications that apply to each criteria type. For aquatic life criteria, there may be up to two types of mixing zones: one for the acute criterion and one for the chronic criterion (see Figure 5.1).

In the zone immediately surrounding the outfall, both the acute and the chronic criteria may be exceeded, but the acute criterion is met at the edge of this zone, which is often referred to as the acute mixing zone or the zone of initial dilution. The acute mixing zone is sized to prevent lethality to passing organisms in order to protect the designated use of the waterbody as a whole.

In the next mixing zone, which is often called the chronic mixing zone, the chronic criterion may be exceeded, but the acute criterion is met. The chronic criterion is met at the edge of the chronic mixing zone. The chronic mixing zone is sized to protect the designated use of the waterbody as a whole.

Where the state or tribe also has human health criteria for the pollutant of concern, the human health mixing zone is sized to prevent significant human risks in order to protect the designated use of the waterbody as a whole.



For a particular pollutant found in a particular discharge, the magnitude, duration, frequency, and any authorized mixing zone associated with each of the criteria types (i.e., human health and acute and chronic aquatic life) will determine which criterion most limits the allowable discharge. In all cases, the permitting authority should evaluate the size of the site-specific mixing zone to determine its effect on the designated use of the waterbody as a whole. Section 2.2.2 of the TSD (1991) contains information for determining whether a mixing zone's size is appropriate.

State and tribal mixing zone policies should identify zones of passage within waterbodies that contain migrating, free-swimming, or drifting organisms. Zones of passage are continuous water routes of such volume, area, and quality as to allow the passage of free swimming and drifting organisms without significant adverse effects on their populations. Many species migrate for spawning and other purposes. Not only do migrating species (e.g., anadromous and catadromous species) need to be able to reach suitable spawning areas, their young (and in some cases the adults) require a safe return route to their growing and living areas. Elevated pollutant concentrations within a mixing zone can create barriers that hinder or prevent safe migration. Therefore, mixing zones should be sized and located appropriately within the waterbody to provide a continuous zone of passage that protects migrating, free-swimming, and drifting organisms.

Shape

The waterbody type, outfall design, and characteristics of the discharge will determine the shape of a mixing zone. The shape should be a simple configuration that is easy to locate in a waterbody and that avoids impingement on biologically important areas. In lakes, a circle with a specified radius is generally preferable, but other shapes may be appropriate in the case of unusual site requirements.

"Shore hugging" plumes should be avoided in all waterbodies. Shore areas are often the most biologically productive and sensitive areas of a waterbody, and they are often used for recreation. Shore-hugging plumes generally do not mix as well with receiving waters and, thus, do not dilute as well as mixing zones with other shapes that do not hug shorelines. Because shore-hugging plumes tend to keep unmixed water over the benthic area or in the recreational area, they are more likely to adversely affect the designated uses of the waterbody.

Outfall Design

Because outfall design affects the amount of initial mixing that occurs, state and tribal mixing zone policies should instruct dischargers to utilize the best practicable engineering design of the outfall to maximize initial mixing. Sometimes, modifying the design of the diffuser, the location of the outfall, or other outfall design characteristics can reduce significant adverse impacts to the waterbody because different design characteristics have different effects on mixing. Many different factors affect how well the outfall design allows the discharge to mix with the receiving water including the following:

- The height of the outfall with respect to the surface and bottom of the waterbody.
- The distance of the end of the pipe to the nearest bank (i.e., whether the outfall is in the middle of the waterbody or close to one side).
- The angle of the discharge.
- The type of diffuser that is used (i.e., single-port or multi-port diffuser).

Section 4.4.1 of the [TSD \(1991\)](#) describes recommendations for outfall design in more detail.

In-zone Water Quality

States and authorized tribes should ensure that a minimum level of water quality is maintained within a mixing zone. Mixing zones should attain the "free from" narrative water quality criteria that are applicable to all waters in a state or reservation. For example, the EPA recommends that mixing zones be free from the following:

- Materials in concentrations that will cause acutely toxic conditions to aquatic life.
- Materials in concentrations that settle to form objectionable deposits.
- Floating debris, oil, scum, and other material in concentrations that form nuisances.
- Substances in concentrations that produce objectionable color, odor, taste, or turbidity.
- Substances in concentrations that produce undesirable aquatic life or result in a dominance of nuisance species.

5.1.2 Situations in Which Mixing Zones May Not Be Appropriate

As discussed above, states and authorized tribes are not required to allow mixing zones. Even if a state or tribe chooses to allow mixing zones generally, it may also choose to define in its policy circumstances under which mixing zones are prohibited (e.g., for particular pollutants and/or waterbodies). Likewise, where the state or tribe generally allows mixing zones, the permitting authority may decide that a mixing zone is not appropriate for a particular discharge on a site-specific basis. ⁴ States and tribes should conclude that mixing zones are not appropriate in the following situations:

- Where they may impair the designated use of the waterbody as a whole.
- Where they contain pollutant concentrations that may be lethal to passing organisms.
- Where they contain pollutant concentrations that may cause significant human health risks considering likely pathways of exposure.
- Where they may endanger critical areas such as breeding and spawning grounds, habitat for threatened or endangered species, areas with sensitive biota, shellfish beds, fisheries, drinking water intakes and sources, and recreational areas.

Additionally, states and tribes should carefully consider whether mixing zones are appropriate where a discharge contains bioaccumulative, pathogenic, persistent, carcinogenic, mutagenic, or teratogenic pollutants or where a discharge containing toxic pollutants may attract aquatic life.

Bioaccumulative pollutants are one example of a pollutant for which mixing zones may not be appropriate because they may cause significant human health risks such that the designated use of the waterbody as a whole may not be protected. ⁵ Therefore, the EPA recommends that state and tribal mixing zone policies do not allow mixing zones for discharges of bioaccumulative pollutants. The EPA adopted this approach in 2000 when it amended its 1995 *Final Water Quality Guidance for the Great Lakes System* at [40 CFR Part 132](#) to phase out mixing zones for existing discharges of bioaccumulative pollutants within the Great Lakes Basin and ban such mixing zones for new discharges within the Basin.

Because fish tissue contamination tends to be a far-field problem affecting entire or downstream waterbodies rather than a near-field problem being confined to the area within a mixing zone, a state or tribe may find it appropriate to restrict or eliminate mixing zones for bioaccumulative pollutants in certain situations such as the following:

- Where mixing zones may encroach on areas often used for fish harvesting, particularly for stationary species such as shellfish.
- Where there are uncertainties in the protectiveness of the water quality criteria or the assimilative capacity of the waterbody.

[Chapter 3](#) of this Handbook and Chapter 5 of *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) provide additional information about bioaccumulation, and Section 4.3.4 of the [TSD \(1991\)](#) discusses preventing bioaccumulation problems for human health in calculating WQBELs.

Another example of a pollutant for which a mixing zone may not be appropriate is bacteria. Because bacteria mixing zones may cause significant human health risks and endanger critical areas (e.g., recreational areas), the EPA recommends that state and tribal mixing zone policies do not allow mixing zones for bacteria in waters designated for primary contact recreation. The presumption in a river or stream segment designated for primary contact recreation is that primary contact recreation can safely occur throughout the segment and, therefore, that bacteria levels will not exceed criteria throughout the segment. Epidemiological studies have demonstrated that illness rates are higher when the criteria are exceeded compared to when those criteria are not exceeded (see Sections 3.2 and 3.3 of the EPA's *Recreational Water Quality Criteria* (2012)). Therefore, people recreating in or through a bacteria mixing zone (where bacteria levels may be elevated above the criteria levels) may be exposed to greater risk of gastrointestinal illness than would otherwise be allowed by the state or tribal criteria for protection of the recreation use. Given this presumption, states and tribes should carefully evaluate whether authorizing a mixing zone that results in elevated levels of bacteria in a river or stream designated for primary contact recreation will adversely affect the designated use. If so, then states and tribes should not authorize such mixing zones because they could result in a significant human health risk.

A third example of a situation in which the EPA recommends that states and tribes prohibit a mixing zone is when an effluent is known to attract biota. In such cases, a continuous zone of passage around the mixing area will not protect aquatic life. Although most toxic pollutants elicit a neutral or avoidance response, there are some situations in which aquatic life are attracted to a toxic discharge and, therefore, can potentially incur significant exposure. For example, temperature can be an attractive force and may counter an avoidance response to a particular pollutant. Therefore, the organisms would tend to stay in the mixing zone rather than passing through or around it. Innate behavior such as migration may also counter an avoidance response and cause fish to incur significant exposure.

5.1.3 Mixing Zones for the Discharge of Dredged or Fill Material

In conjunction with the Department of the Army, the EPA has developed guidelines at [40 CFR Part 230](#) for evaluating discharges of dredged or fill material into navigable waters, which include provisions at 40 CFR 230.11(f) for determining the acceptability of mixing zones for such material. Discharges of dredged or fill material are generally temporary and result in short term disruption to the waterbody rather than constituting a continuous discharge with long-term disruption beyond the fill area. In authorizing and establishing mixing zones for dredge and fill activities, the state or authorized tribe's primary consideration should be achieving and protecting the designated uses of the waterbody pursuant to [40 CFR 131.10](#). As such, states and tribes should evaluate the particular pollutants involved for their effects on the designated use. Technical guidance for determining the potential for contaminant-related impacts associated with the discharge of dredged material can be found in [Evaluation of Dredged Material Proposed for Discharge in Waters of the U.S. – Testing Manual: Inland Testing Manual \(1998\)](#).

5.1.4 Mixing Zones for Aquaculture Projects

Under Section 318 of the [CWA](#), permitting authorities may allow discharges of certain pollutants associated with approved aquaculture projects. Consistent with [40 CFR 122.25](#), an aquaculture project is a defined, managed water area into which certain pollutants are discharged for the maintenance or production of harvestable freshwater, estuarine, or marine plants or animals. The EPA's regulations at [40 CFR 125.11](#) provide that aquaculture project approval must not result in the enlargement of a pre-existing mixing zone beyond the area designated for the original discharge and that the designated project area (which is also defined at 40 CFR 122.25) must not include a portion of a waterbody large enough to expose a substantial portion of the indigenous biota to the conditions within the designated project area. For example, a designated project area should not include the entire width of a stream because all of the indigenous organisms might be exposed to pollutant discharges that would exceed WQS. The areas designated for approved aquaculture projects should be treated in the same manner as other mixing zones.

5.2 Critical Low Flows for Water Quality Criteria Implementation

Pursuant to [40 CFR 131.11\(a\)](#), states and authorized tribes must adopt those water quality criteria that protect designated uses. To ensure that adopted criteria are protective of the designated uses, states and tribes generally establish critical low-flow values to support implementation of the applicable criteria through such programs as NPDES permitting.

Critical low-flow conditions present special challenges to the integrity of the aquatic community and the protection of human health. Dilution is one of the primary mechanisms by which the concentrations of contaminants in effluent discharges are reduced following their introduction into a receiving water. Low flows in the receiving water typically aggravate the effects of effluent discharges because, during a low-flow event, there is less water available for dilution, resulting in higher instream concentrations of pollutants. Therefore, the allowable dilution (which may be only a portion of the critical low flow depending on the state or tribal WQS and implementation procedures) for purposes of determining the need for and establishing WQBELs in NPDES permits should ensure protection of the applicable criteria at the calculated critical low-flow value.

The EPA has historically encouraged states and tribes to specify directly within their WQS which calculated critical low-flow values should be used to determine the available dilution for the purposes of determining the need for and establishing WQBELs. Such critical low-flow values have historically been reviewed and approved or disapproved by the EPA as new or revised WQS under Section 303(c) of the [CWA](#). Likewise, revisions to those critical low-flow values would generally constitute new or revised WQS subject to EPA review and approval or disapproval (see [Chapter 1](#) of this Handbook and [What is a New or Revised Water Quality Standard Under CWA Section 303\(c\)? Frequently Asked Questions \(20123\) \(PDF\)](#)) (4 pp, 108K, [About PDF](#)).

Most states and tribes generally follow the guidance in the [TSD \(1991\)](#) when adopting critical low-flow values for criteria implementation. The EPA recommends that states and tribes adopt the critical low-flow values for use in steady-state analyses so that criteria are implemented appropriately. If criteria are implemented using inappropriate critical low-flow values (i.e., calculated values that are too high), the resulting control of toxic pollutants may not be fully protective because the resulting ambient concentrations could exceed criteria when such low flows occur. In the case of aquatic life, more frequent excursions than are allowable (e.g., more than once in three years) could result in unacceptable effects on aquatic organisms and designated uses if the appropriate value is not used in the calculations.

In addition to steady-state models, the TSD recommends the use of three dynamic models to perform wasteload allocations. Because dynamic wasteload models do not generally use specific steady-state critical low-flow values but accomplish the same effect by factoring in the probability of occurrence of stream flows based on the historical flow record, this Handbook discusses only steady-state conditions.

In Appendix D of the TSD and [Technical Guidance Manual for Performing Wasteload Allocations, Book VI: Design Conditions – Chapter 1: Stream Design Flow for Steady-State Modeling \(1986\)](#), the EPA describes and recommends two methods for calculating acceptable critical low-flow values: the traditional hydrologically based method developed by the United States Geological Survey (USGS) and a biologically based method developed by the EPA.⁴¹ The hydrologically based critical low-flow value is determined statistically using probability and extreme values, while the biologically based critical low flow is determined empirically using the specific duration and frequency associated with the criterion.

Additionally, the two documents listed above describe the flow values that the EPA recommends for implementing acute and chronic criteria using both methods. Table 5.1 below summarizes these recommendations.

Table 5.1: EPA-recommended Critical Low Flows for Aquatic Life and Human Health Criteria

Criteria	Hydrologically Based Flow	Biologically Based Flow
Acute Aquatic Life	1Q10	1B3
Chronic Aquatic Life	7Q10	4B3
Human Health	Harmonic mean	

Using the hydrologically based method, 1Q10 represents the lowest one-day average flow event expected to occur once

every ten years, on average, and 7Q10 represents the lowest seven-consecutive-day average flow event expected to occur once every ten years, on average. Using the biologically based method, 1B3 represents the lowest one-day average flow event expected to occur once every three years, on average, and 4B3 represents the lowest four-consecutive-day average flow event expected to occur once every three years, on average.

States and tribes may designate other critical low-flow values to implement the applicable criteria, provided they are scientifically justified. The EPA has also recommended critical low-flow values that differ from the above recommendations for specific pollutants such as 30Q5, 30Q10, and 30B3 for implementing chronic criteria for ammonia.

The EPA does not view the fact that many streams within a state or tribe have no flow at 7Q10 as adequate justification for designating alternative flows. Note that, when a criterion specifies a four day average concentration that should not be exceeded more than once every three years, this condition should not be interpreted as implying that a 4Q3 low flow is appropriate for use as the hydrologically based critical low-flow value for assessing impacts on the receiving water.

The EPA recommends the harmonic mean flow for implementing human health criteria. The concept of a harmonic mean is a standard statistical data analysis technique. The EPA's model for human health effects assumes that such effects occur because of a long-term exposure to low concentrations of a toxic pollutant (e.g., two liters of water per day for seventy years). The harmonic mean flow allows for estimating the concentration of toxic pollutant contained in those two liters of water per day when the daily variation in the flow rate is high. Therefore, the EPA recommends use of the harmonic mean flow in computing critical low flows for human health criteria rather than using other averaging techniques.

In addition to the documents listed above, see the EPA's [Flow 101 webpage](#) and [Advanced Notice of Proposed Rulemaking for Water Quality Standards \(1998\)](#) for additional information on critical low flows.

The EPA notes that the USGS has documented that, in some areas of the United States, there have been changes to the critical low flows in freshwater rivers and streams or increased duration and frequency of low flow occurrence. The source of the reductions may often be anthropogenic in origin such as over-pumping of groundwater, hydrologic alteration including impoundments, or surface water withdrawals. Some of these reductions may persist long enough to cause changes to the critical low-flow values. In addition, prolonged droughts have resulted in a reduction of the low-flow minimums released on regulated rivers or revisions to drought control manuals to allow for further reductions of the low-flow values. During prolonged droughts, there may also be a trend towards increased pumping of groundwater, which may, in turn, lead to a reduction of surface water flows. New water intakes may also permanently change a waterbody's critical low flow.

The following documents provide additional information on changing flow patterns:

- The USGS's [National Water Census - Streamflow webpage](#).
- The USGS's [Groundwater Depletion in the United States \(1900-2008\) \(2013\)](#).
- The USGS's [Alteration of Streamflow Magnitudes and Potential Ecological Consequences: a Multiregional Assessment \(2011\)](#).
- The EPA's [Report on the Environment - Fresh Surface Water webpage](#).

It may be prudent for states and tribes to review and revise, as appropriate, their critical low-flow values during the triennial review process to account for changes to historical flow patterns. Also, NPDES permitting authorities should be aware that these altered historical flow patterns in rivers and streams may render historical flow records less accurate in predicting current and future critical flows. Where appropriate, permitting authorities should consider alternate approaches to establishing critical low-flow conditions that account for these climatic and anthropogenic changes when conducting reasonable potential analyses and in establishing protective WQBELs (see [NPDES Permit Writers' Manual: Inclusion of Climate Change Considerations](#)).

5.3 Variances from Water Quality Standards

A WQS variance is a time-limited designated use and water quality criterion for a specific pollutant(s) or water quality parameter(s) that reflect the highest attainable condition during the term of the WQS variance. A WQS variance may apply to an NPDES-permitted discharger or waterbody/waterbody segment(s). The regulation at [40 CFR 131.13](#) provides that states and authorized tribes may adopt into their WQS general variance policies that describe how they intend to apply and implement variances. Although such variance policies require EPA review and approval, states and tribes are not required to adopt variance policies in order to adopt individual variances. Nevertheless, as opposed to individual mixing zones (discussed in Section 5.1 of this chapter), the individual variances themselves must be adopted into WQS (or other legally binding state or tribal requirements) and approved by the EPA before they can be effective for [CWA](#) purposes.

Although the legal authority to adopt a WQS variance is the same as a revision to a designated use, the purpose of a variance is different from that of a designated use revision (described in [Chapter 2](#) of this Handbook). A variance is intended to serve as a mechanism to provide time for states, tribes, and stakeholders to implement actions to improve water quality over an identified period of time when and where the designated use currently in place is not being met. When utilizing a variance, the state or tribe retains the designated use that is currently in place as a long-term goal. As first articulated in 1977 in [Decision of the General Counsel on Matters of Law Pursuant to 40 CFR Section 125.36\(m\), No. 58](#), a state or tribe may adopt a WQS variance if the state or tribe can satisfy the same substantive and procedural requirements as a designated use removal, which are described in [40 CFR 131.10\(g\)](#).

A variance is also different from a permit compliance schedule. While both tools can provide time to meet regulatory requirements, which tool is appropriate depends upon the circumstances. Variances can be appropriate to address situations where it is known that the designated use and criterion are unattainable today (or for a limited period of time), but feasible progress could be made toward attaining the designated use and criterion. A permit compliance schedule, on the other hand, may be appropriate when the designated use is attainable, but the discharger needs additional time to modify or upgrade treatment facilities in order to meet its WQBEL such that a schedule and resulting milestones will lead to compliance "as soon as possible" with the WQBEL based on the currently applicable WQS. See CWA Section 502(17) for a definition of "schedules of compliance" and [40 CFR 122.47](#).

A variance may be appropriate where a state or tribe determines that the designated use cannot be attained for a period of time because the discharger cannot immediately meet a WQBEL, which is written to meet a particular WQS, or a waterbody/waterbody segment cannot immediately meet the criteria to protect the designated use. Under such circumstances, the variance provides a targeted, time-limited revision to the WQS that reflects the highest attainable condition. These new time-limited WQS then serve as the basis for pollution control requirements during the term of the variance. For WQS variances that apply to aquatic life, wildlife, and recreational uses (i.e., the Section 101(a)(2) uses), this means that attainment of the designated use is infeasible under at least one of the six factors at [131.10\(g\)](#) for at least the term of the variance.

The practical effect of the variance is an NPDES permit containing a WQBEL that complies with a less stringent criterion than would otherwise be in effect in the absence of the variance. However, the underlying designated use and criteria remain in effect for Section 303(d) listing and total maximum daily load development regardless of whether the variance is for a single discharger, multiple dischargers, or a waterbody/waterbody segment. At the end of the variance term, the discharger's WQBEL must ensure compliance with the underlying designated use and criterion or the state or tribe must obtain a new variance. To obtain a new variance, the state or tribe must again demonstrate that the designated use is not attainable at the point of discharge and again submit the variance to the EPA for review and approval or disapproval.

In many cases, a WQS variance is an environmentally useful tool because a variance exists only for a defined term and retains designated use protection for all pollutants and sources, with the sole exception of those specified in the variance. Even the discharger with a variance for a particular pollutant is required to meet applicable criteria for all other pollutants. Thus, a variance can result in water quality improvements over time and, in some cases, full attainment of designated uses by maintaining existing water quality protections while allowing time for advances in treatment technologies, control practices, or other changes in circumstances.

States and tribes typically adopt a WQS variance for an individual discharger for a specific pollutant in a specific waterbody. However, where multiple dischargers have similar attainment challenges, a state or tribe may streamline its variance process by adopting a multiple-discharger WQS variance. Such a variance applies to several dischargers but may be supported by a single technical rationale justifying the need for the variance. The EPA has previously published information on both individual- and multiple-discharger variances at [40 CFR Part 132](#). For additional information on variances, also see [Discharger-Specific Variances on a Broader Scale: Developing Credible Rationales for Variances that Apply to Multiple Dischargers \(2013\)](#).

^{1/} Throughout this document, the term "states" means the fifty states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The term "authorized tribe" or "tribe" means an Indian tribe authorized for treatment in a manner similar to a state under [CWA](#) Section 518 for purposes of Section 303(c) WQS.

^{2/} Lethality is a function of the magnitude of a pollutant concentration and the duration an organism is exposed to that concentration. Section 4.3.3 of the [TSD \(1991\)](#) describes various methods for preventing lethality to organisms passing through a mixing zone.

^{3/} Acutely toxic conditions are those that are lethal to aquatic organisms that may pass through the mixing zone. The underlying assumption for allowing a mixing zone is that pollutant concentrations in excess of acute and chronic criteria, but below acutely toxic concentrations, may exist in small areas without causing adverse effects to the designated use of the waterbody as a whole.

^{4/} The 1996 memorandum [EPA Guidance on Application of State Mixing Zone Policies in EPA-issued NPDES Permits](#) describes the circumstances under which the EPA may include a mixing zone in an NPDES permit when the EPA is the permitting authority.

^{5/} However, note that some chemicals of relatively low toxicity such as zinc will bioconcentrate in fish without harmful effects resulting from human consumption.

^{6/} In some EPA documents such as those cited, critical low flow is also called "design flow" or "stream design flow." These terms are different from a facility or effluent design flow.

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Water Quality Standards Handbook - Chapter 3: Water Quality Criteria (40 CFR 131.11)

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The term "water quality criteria" has two different definitions under the Clean Water Act (CWA). Under section 304(a), EPA publishes water quality criteria that consist of scientific information regarding concentrations of specific chemicals or levels of parameters in water that protect aquatic life and human health (see section 3.1 of this Handbook). The States may use these contents as the basis for developing enforceable water quality standards. Water quality criteria are also elements of State water quality standards adopted under section 303(c) of the CWA (see sections 3.2 through 3.6 of this Handbook). States are required to adopt water quality criteria that will protect the designated use(s) of a water body. These criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.

3.1 EPA Section 304(a) Guidance

EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were the "Green Book" (FWPCA, 1968) and the "Red Book" (USEPA, 1976). EPA also sponsored a contract effort that resulted in the "Blue Book" (NAS/NAE, 1973). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate because essential information was not available for many pollutants. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants (USEPA, 1980a,b). Since that initial publication, the aquatic life methodology was amended (Appendix H), and additional criteria were proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in the "Gold Book" (USEPA, 1986a), which is updated from time to time. However, the individual criteria documents (see Appendix I), as updated, are the official guidance documents.

EPA's criteria documents provide a comprehensive toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute

Updated Information

National Recommended Water Quality Criteria

- [Current National Recommended Criteria](#) - This compilation of national recommended water quality criteria is presented as a summary table containing recommended water quality criteria for the protection of aquatic life and human health in surface water for approximately 150 pollutants.
- [Water Quality Standards and Criteria Strategy \(2003\)](#) - This website describes milestones for high priority strategic actions that were established in 2003, including issuing implementation guidance for bacteria criteria, developing

criteria) and criteria continuous concentrations (chronic criteria) that the Agency recommends to protect aquatic life resources. The methodologies for these processes are described in Appendices H and J and outlined in sections 3.1.2 and 3.1.3 of this Handbook.

—3.1.1 State Use of EPA Criteria Documents

EPA's water quality criteria documents are available to assist States in:

- adopting water quality standards that include appropriate numeric water quality criteria;
- interpreting existing water quality standards that include narrative "no toxics in toxic amounts" criteria;
- making listing decisions under section 304(1) of the CWA;
- writing water quality-based NPDES permits and individual control strategies; and
- providing certification under section 401 of the CWA for any Federal permit or license (e.g., EPA-issued NPDES permits, CWA section 404 permits, or Federal Energy Regulatory Commission licenses).

In these situations, States have primary authority to determine the appropriate level to protect human health or welfare (in accordance with section 303(c)(2) of the CWA) for each water body. However, under the Clean Water Act, EPA must also review and approve State water quality standards; section 304(1) listing decisions and draft and final State-issued individual control strategies; and in States where EPA writes NPDES permits, EPA must develop appropriate water quality-based permit limitations. The States and EPA therefore have a strong interest in assuring that the decisions are legally defensible, are based on the best information available, and are subject to full and meaningful public comment and participation. It is very important that each decision be supported by an adequate record. Such a record is critical to meaningful comment, EPA's review of the State's decision, and any subsequent administrative or judicial review.

Any human health criterion for a toxicant is based on at least three interrelated considerations:

- cancer potency or systemic toxicity,
- exposure, and
- risk characterization.

States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments, when different from EPA's recommendation, must be clear and in the public record. If a State relies on EPA's section 304(a) criteria document (or other EPA documents), the State may reference and rely on the data in these documents and need not create duplicative or new material for inclusion in their records. However, where site-specific issues arise or the State decides to adopt an approach to any one of these three factors that differs from the approach in EPA's criteria document, the State must explain its reasons in a manner sufficient for a reviewer to determine that the approach chosen is based on sound scientific rationale (40 CFR 131.11 (b)).

—3.1.2 Criteria for Aquatic Life Protection

The development of national numerical water quality criteria for the protection of aquatic organisms is a complex process that uses information from many areas of aquatic toxicology. (See [Appendix H \(PDF\)](#) (18 pp, 1.5MB) for a detailed discussion of this process.) After a decision is made that a national criterion is needed for a particular material, all available information concerning toxicity to, and bioaccumulation by, aquatic organisms is collected and reviewed for acceptability. If enough acceptable data for 48- to 96-hour toxicity tests on aquatic plants and animals are available, they are used to derive the acute criterion. If sufficient data on the ratio of acute to chronic toxicity concentrations are available, they are used to derive the chronic or long-term exposure criteria. If justified, one or both of the criteria may be related to other water quality characteristics, such as pH, temperature, or hardness. Separate criteria are developed for fresh and salt waters.

The Water Quality Standards Regulation allows States to develop numerical criteria or modify EPA's recommended criteria to account for site-specific or other scientifically defensible factors. Guidance on modifying national criteria is found in sections 3.6 and 3.7. When a criterion must be developed for a chemical for which a national criterion has not been established, the regulatory authority should refer to the EPA guidelines ([Appendix H](#)) (PDF) (18 pp, 1.5MB).

Magnitude for Aquatic Life Criteria

Water quality criteria for aquatic life contain two expressions of allowable magnitude: a criterion maximum concentration (CMC) to protect against acute (short-term) effects; and a criterion continuous concentration (CCC) to protect against chronic (long-term) effects. EPA derives acute criteria from 48- to 96-hour tests of lethality or immobilization. EPA derives chronic criteria from longer term (often greater than 28-day) tests that measure survival, growth, or reproduction. Where appropriate, the calculated criteria may be lowered to be protective of commercially or recreationally important species.

Duration for Aquatic Life Criteria

The quality of an ambient water typically varies in response to variations of effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing constant, steady exposure but rather are experiencing fluctuating exposures, including periods of high concentrations, which may have adverse effects. Thus, EPA's criteria indicate a time period over which exposure is to be averaged, as well as an upper limit on the average concentration, thereby limiting the duration of exposure to

pathogen and sediment criteria, and developing a selection process for producing new or revised chemical criteria.

Federal Rules Involving Water Quality Criteria

- [Final Water Quality Standards for the State of Florida's Lakes and Flowing Waters \(2010\)](#) - This action established numeric nutrient criteria for Florida's inland waters.
- [Bacteria Rule for Coastal and Great Lakes Waters \(2004\)](#) - This rule established more protective health-based federal bacteria standards for those states and territories bordering Great Lakes or ocean waters that have not yet adopted standards in accordance with the BEACH Act of 2000.
- [Water Quality Standards for Puerto Rico \(2004\)](#) - Promulgated primary contact Recreation Uses and associated water quality criteria for six water bodies.
- [Establishment of Numeric Criteria for Priority Pollutants for the State of California \(2000\)](#) - EPA promulgated this rule to fill a gap in California water quality standards that was created in 1994 when a State court overturned the State's water quality control plans containing water quality criteria for priority toxic pollutants. Between 1994 and 2000 the State of California lacked numeric water quality criteria required by the Clean Water Act for many priority toxic pollutants, necessitating this action by EPA.
- [Beaches Environmental Assessment and Coastal Health Act \(BEACH Act\) of 2000](#) - The BEACH Act established uniform criteria for testing, monitoring, and notifying public users of possible coastal recreation water problems.
- [Advanced Notice of Proposed Rulemaking for Water Quality Standards \(1998\)](#) | [Print Version \(PDF\)](#) (66 pp, 474K) - See pages 36762 to 36778 for and overview of water quality criteria policy and EPA's thinking on program development in 1998.
- [Final Water Quality Guidance for the Great Lakes System \(1995\)](#) This guidance contains numeric criteria to protect aquatic life for 15 pollutants and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System.
- [National Toxics Rule \(1992\)](#) - This EPA action promulgates for 14 States the chemical-specific, numeric criteria for priority toxic pollutants necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act (CWA).

Updated Information

- [Aquatic Life Criteria](#) - This website provides basic information on 304(a) recommended criteria for the protection of aquatic life. This page also provides updates on criteria development.
- [Aquatic Life: Contaminants of Emerging Concern \(2008\)](#) - This white paper details technical issues and recommendations for deriving ambient water quality criteria for aquatic life for contaminants of emerging concern.
- [Water Quality Models and Tools](#) - This website provides access to a number of specialized models and tools for water quality managers, including those related to criteria.

elevated concentrations. For acute criteria, EPA recommends an averaging period of 1 hour. That is, to protect against acute effects, the 1-hour average exposure should not exceed the CMC. For chronic criteria, EPA recommends an averaging period of 4 days. That is, the 4-day average exposure should not exceed the CCC.

Frequency for Aquatic Life Criteria

To predict or ascertain the attainment of criteria, it is necessary to specify the allowable frequency for exceeding the criteria. This is because it is statistically impossible to project that criteria will never be exceeded. As ecological communities are naturally subjected to a series of stresses, the allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stresses combined.

EPA recommends an average frequency for excursions of both acute and chronic criteria not to exceed once in 3 years. In all cases, the recommended frequency applies to actual ambient concentrations, and excludes the influence of measurement imprecision. EPA established its recommended frequency as part of its guidelines for deriving criteria ([Appendix H \(PDF\)](#)) (18 pp, 1.5 MB). EPA selected the 3-year average frequency of criteria exceedence with the intent of providing for ecological recovery from a variety of severe stresses. This return interval is roughly equivalent to a 7Q10 design flow condition. Because of the nature of the ecological recovery studies available, the severity of criteria excursions could not be rigorously related to the resulting ecological impacts. Nevertheless, EPA derives its criteria intending that a single marginal criteria excursion (i.e., a slight excursion over a 1-hour period for acute or over a 4-day period for chronic) would require little or no time for recovery. If the frequency of marginal criteria excursions is not high, it can be shown that the frequency of severe stresses, requiring measurable recovery periods, would be extremely small. EPA thus expects the 3-year return interval to provide a very high degree of protection.

—3.1.3 Criteria for Human Health Protection

This section reviews EPA's procedures used to develop assessments of human health effects in developing water quality criteria and reference ambient concentrations. A more complete human health effects discussion is included in the *Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Documents*. The procedures contained in this document are used in the development and updating of EPA water quality criteria and may be used in updating State criteria and in developing State criteria for those pollutants lacking EPA human health criteria. The procedures may also be applied as site-specific interpretations of narrative standards and as a basis for permit limits under 40 CFR 122.44 (d)(1)(vi).

Magnitude and Duration

Water quality criteria for human health contain only a single expression of allowable magnitude; a criterion concentration generally to protect against long-term (chronic) human health effects. Currently, national policy and prevailing opinion in the expert community establish that the duration for human health criteria for carcinogens should be derived assuming lifetime exposure, taken to be a 70-year time period. The duration of exposure assumed in deriving criteria for noncarcinogens is more complicated owing to a wide variety of endpoints: some developmental (and thus age-specific and perhaps gender-specific), some lifetime, and some, such as organoleptic effects, not duration-related at all. Thus, appropriate durations depend on the individual noncarcinogenic pollutants and the endpoints or adverse effects being considered.

Human Exposure Considerations

A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes. The more important of these include recreational and occupational contact, dietary intake from other than fish, intake from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available (see 45 F.R. 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only (57 F.R. 60862-3).

The consumption of contaminated fish tissue is of serious concern because the presence of even extremely low ambient concentrations of bioaccumulative pollutants (sublethal to aquatic life) in surface waters can result in residue concentrations in fish tissue that can pose a human health risk. Other exposure route information should be considered and incorporated in human exposure evaluations to the extent available.

Levels of actual human exposures from consuming contaminated fish vary depending upon a number of case-specific consumption factors. These factors include type of fish species consumed, type of fish tissue consumed, tissue lipid content, consumption rate and pattern, and food preparation practices. In addition, depending on the spatial variability in the fishery area, the behavior of the fish species, and the point of application of the criterion, the average exposure of fish may be only a small fraction of the expected exposure at the point of application of the criterion. If an effluent attracts fish, the average exposure might be greater than the expected exposure.

With shellfish, such as oysters, snails, and mussels, whole-body tissue consumption commonly occurs, whereas with fish, muscle tissue and roe are most commonly eaten. This difference in the types of tissues consumed has implications for the amount of available bioaccumulative contaminants likely to be ingested. Whole-body shellfish consumption presumably means ingestion of the entire burden of bioaccumulative contaminants. However, with most fish, selective cleaning and removal of internal organs, and sometimes body fat as well, from edible tissues, may result in removal of much of the lipid material in which bioaccumulative contaminants tend to concentrate.

Fish Consumption Values

EPA's human health criteria have assumed a human body weight of 70 kg and the consumption of 6.5 g of fish and shellfish per day. Based on data collected in 1973-74, the national per capita consumption of freshwater and estuarine fish was estimated to average 6.5 g/day. Per capita consumption of all seafood (including marine species) was estimated to average 14.3 g/day. The 95th percentile for consumption of all seafood by individuals over a period of 1 month was estimated to be 42 g/day. The mean lipid content of fish and shellfish tissue consumed in this study was estimated to be 3.0 percent (USEPA, 1980c).

Updated Information

- [Water Quality Criteria for Human Health](#) – This website provides basic information on 304(a) recommended criteria for the protection of human health. The page also provides updates on criteria development.
- [Water Quality Criteria: Microbial](#) – This website provides access to a variety of scientific assessments that are used to protect humans from exposure to harmful levels of pathogens in ground and surface waters, food sources, and finished drinking water.
- [Recreational Water Quality Criteria \(2011\)](#) – This website provides information on developing criteria for the protection of contact recreation activities such as swimming, bathing, surfing, or similar water contact activities due to exposure to fecal contamination in surface waters.
- [National Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories \(2000\)](#) – Provides guidance for assessing health risks associated with the consumption of chemically contaminated non-commercial fish.
- [Integrated Risk Information System \(IRIS\) Database of Human Health Effects](#) – IRIS is a human health assessment program that evaluates risk information on effects that may result from exposure to environmental contaminants.
- [Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions \(2013\)](#) – Frequently asked questions on deriving fish consumption rates and applying relative source contributions for use in deriving ambient water quality criteria for the protection of human health.

Currently, four levels of fish and shellfish consumption are provided in EPA guidance (USEPA, 1991a):

- 6.5 g/day to represent an estimate of average consumption of fish and shellfish from estuarine and freshwaters by the entire U.S. population. This consumption level is based on the average of both consumers and nonconsumers of.
- 20 g/day to represent an estimate of the average consumption of fish and shellfish from marine, estuarine, and freshwaters by the U.S. population. This average consumption level also includes both consumers and nonconsumers of.
- 165 g/day to represent consumption of fish and shellfish from marine, estuarine, and freshwaters by the 99.9th percentile of the U.S. population consuming the most fish or seafood.
- 180 g/day to represent a "reasonable worst case" based on the assumption that some individuals would consume fish and shellfish at a rate equal to the combined consumption of red meat, poultry, fish, and shellfish in the United States.

EPA is currently updating the national estuarine and freshwater fish and shellfish consumption default values and will provide a range of recommended national consumption values. This range will include:

- mean values appropriate to the population at large; and
- values appropriate for those individuals who consume a relatively large proportion of fish and shellfish in their diets (maximally exposed individuals).

Many States use EPA's 6.5 g/day consumption value. However, some States use the above-mentioned 20 g/day value and, for saltwaters, 37 g/day. In general, EPA recommends that the consumption values used in deriving criteria from the formulas in this chapter reflect the most current, relevant, and/or site-specific information available.

Bioaccumulation Considerations

The ratio of the contaminant concentrations in fish tissue versus that in water is termed either the bioconcentration factor (BCF) or the bioaccumulation factor (BAF). Bioconcentration is defined as involving contaminant uptake from water only (not from food). The bioaccumulation factor (BAF) is defined similarly to the BCF except that it includes contaminant uptake from both water and food. Under laboratory conditions, measurements of tissue/water partitioning are generally considered to involve uptake from water only. On the other hand, both processes are likely to apply in the field since the entire food chain is exposed.

The BAF/BCF ratio ranges from 1 to 100, with the highest ratios applying to organisms in higher trophic levels, and to chemicals with logarithm of the octanol-water partitioning coefficient (log P) close to 6.5.

Bioaccumulation considerations are integrated into the criteria equations by using food chain multipliers (FMs) in conjunction with the BCF. The bioaccumulation and bioconcentration factors for a chemical are related as follows: $BAF = FM \times BCF$.

By incorporating the FM and BCF terms into the criteria equations, bioaccumulation can be addressed.

In Table 3-1, FM values derived from the work of Thomann (1987, 1989) are listed according to log P value and trophic level of the organism. For chemicals with log P values greater than about 7, there is additional uncertainty regarding the degree of bioaccumulation, but generally, trophic level effects appear to decrease due to slow transport kinetics of these chemicals in fish, the growth rate of the fish, and the chemical's relatively low bioavailability. Trophic level 4 organisms are typically the most desirable species for sport fishing and, therefore, FMs for trophic level 4 should generally be used in the equations for calculating criteria. In those very rare situations where only lower trophic level organisms are found, e.g., possibly oyster beds, an FM for a lower trophic level might be considered.

Measured BAFs (especially for those chemicals with log P values above 6.5) reported in the literature should be used when available. To use experimentally measured BAFs in calculating the criterion, the (FM x BCF) term is replaced by the BAF in the equations in the following section. Relatively few BAFs have been measured accurately and reported, and their application to sites other than the specific ecosystem where they were developed is problematic and subject to uncertainty. The option is also available to develop BAFs experimentally, but this will be extremely resource intensive if done on a site-specific basis with all the necessary experimental and quality controls.

Table 3-1. Estimated Food Chain Multipliers (FMs)

Trophic Levels			
Log P	2	3	4
3.5	1.0	1.0	1.0
3.6	1.0	1.0	1.0
3.7	1.0	1.0	1.0
3.8	1.0	1.0	1.0
3.9	1.0	1.0	1.0
4.0	1.1	1.0	1.0
4.1	1.1	1.1	1.1
4.1	1.1	1.1	1.1
4.2	1.1	1.1	1.1
4.3	1.1	1.1	1.1
4.4	1.2	1.1	1.1
4.5	1.2	1.2	1.2
4.6	1.2	1.3	1.3

Trophic Levels

Log P	2	3	4
4.7	1.3	1.4	1.4
4.8	1.4	1.5	1.5
4.9	1.5	1.8	2.0
5.0	1.6	2.1	2.6
5.1	1.7	2.5	3.2
5.2	1.9	3.0	4.3
5.3	2.2	3.7	5.8
5.4	2.4	4.6	8.0
5.5	2.8	5.9	11.0
5.6	3.3	7.5	16.0
5.7	3.9	9.8	23.0
5.8	4.6	13.0	33.0
5.9	5.6	17.0	47.0
6.0	6.8	21.0	67.0
6.1	8.2	25.0	75.0
6.2	10.0	29.0	84.0
6.3	13.0	34.0	84.0
6.4	13.0	34.0	84.0
6.5	19.0	45.0	100.0
≥6.5	19.2*	45.0*	100.0*

* These recommended FMs are conservative estimates; FMs for log P values greater than 6.5 may range from the values given to a low as 0.1 for contaminants with very low bioavailability.

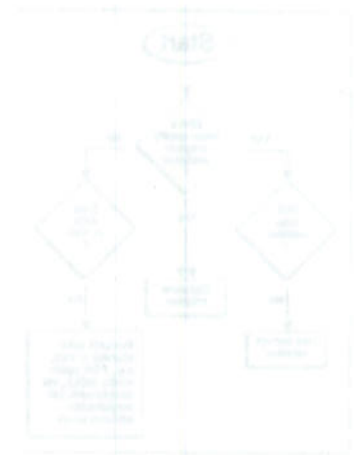
Updating Human Health Criteria Using IRIS

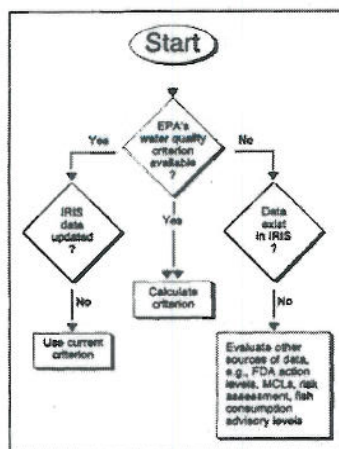
EPA recommends that States use the most current risk information in the process of updating human health criteria. The Integrated Risk Information System (IRIS) (Barns and Dourson, 1988; Appendix N) is an electronic data base of the USEPA that provides chemical-specific risk information on the relationship between chemical exposure and estimated human health effects. Risk assessment information contained in IRIS, except as specifically noted, has been reviewed and agreed upon by an interdisciplinary group of scientists representing various Program Offices within the Agency and represent an Agency-wide consensus. Risk assessment information and values are updated on a monthly basis and are approved for Agency-wide use. IRIS is intended to make risk assessment information readily available to those individuals who must perform risk assessments and also to increase consistency among risk assessment/risk management decisions.

IRIS contains two types of quantitative risks values: the oral Reference Dose (RfD) and the carcinogenic potency estimate or slope factor. The RfD (formerly known as the acceptable daily intake or ADI) is the human health hazard assessment for noncarcinogenic (target organ) effects. The carcinogenic potency estimate (formerly known as q₁) represents the upper bound cancer-causing potential resulting from lifetime exposure to a substance. The RfD or the oral carcinogenic potency estimate is used in the derivation of EPA human health criteria.

EPA periodically updates risk assessment information, including RfDs, cancer potency estimates, and related information on contaminant effects, and reports the current information on IRIS. Since IRIS contains the Agency's most recent quantitative risk assessment values, current IRIS values should be used by States in updating or developing new human health criteria. This means that the 1980 human health criteria should be updated with the latest IRIS values. The procedure for deriving an updated human health water quality criterion would require inserting the current RfD or carcinogenic potency estimate on IRIS into the equations in Exhibit 3.1 or 3.2, as appropriate.

Figure 3-1 shows the procedure for determining an updated criterion using IRIS data. If a chemical has both carcinogenic and non-carcinogenic effects, i.e., both a cancer potency estimate and a RfD, both criteria should be calculated. The most stringent criterion applies.





Calculating Criteria for Non-carcinogens

The RfD is an estimate of the daily exposure to the human population that is likely to be without appreciable risk of causing deleterious effects during a lifetime. The RfD is expressed in units of mg toxicant per kg human body weight per day.

RfDs are derived from the "no-observed-adverse-effect level" (NOAEL) or the "lowest-observed-adverse-effect level" (LOAEL) identified from chronic or subchronic human epidemiology studies or animal exposure studies. (Note: "LOAEL" and "NOAEL" refer to animal and human toxicology and are therefore distinct from the atpl3tiC toxicity terms "no-observed-effect concentration" (NOEC) and "lowest-observed-effect concentration" (LOEC).) Uncertainty factors are then applied to the NOAEL or LOAEL to account for uncertainties in the data associated with variability among individuals, extrapolation from nonhuman test species to humans, data on other than long-term exposures, and the use of a LOAEL (USEPA, 1988a). An additional uncertainty factor may be applied to account for significant weakness or gaps in the database.

The RfD is a threshold below which systemic toxic effects are unlikely to occur. While exposures above the RfD increase the probability of adverse effects, they do not produce a certainty of adverse effects. Similarly, while exposure at or below the RfD reduces the probability, it does not guarantee the absence of effects in all persons. The RfDs contained in IRIS are values that represent EPA's consensus (and have uncertainty spanning perhaps an order of magnitude). This means an RfD of 1.0 mg/kg/day could range from 0.3 to 3.0 mg/kg/day.

For noncarcinogenic effects, an updated criterion can be derived using the equation in [Exhibit 3-1](#).

If the receiving water body is not used as a drinking water source, the factor WI can be deleted. Where dietary and/or inhalation exposure values are unknown, these factors may be deleted from the above calculation.

Exhibit 3-1. Equation for Deriving Human Health Criteria Based on Noncarcinogenic Effects

$$C \text{ (mg/l)} = \frac{RfD \times WT - (DT + IN) \times WT}{WT + [FC \times L \times FM \times BCF]}$$

where:

- C =
updated water quality criteria (mg/l)
- RfD =
oral reference dose (mg toxicant/kg human body weight/day)
- WT =
weight of an average human adult (70 kg)
- DT =
dietary exposure (other than fish) (mg toxicant/kg body human weight/day)
- IN =
inhalation exposure (mg toxicant/kg body human weight/day)
- WI =
average human adult water intake (2 l/day)
- FC =
daily fish consumption (kg fish/day)
- L =

ratio of lipid fraction of fish tissue consumed to 3%

- FM =
food chain multiplier (from [Table 3-1](#))
- BCF =
bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/L water) for fish with 3% lipid content

Calculating Criteria for Carcinogens

Any human health criterion for a carcinogen is based on at least three interrelated considerations: cancer potency, exposure, and risk characterization. When developing State criteria, States may make their own judgments on each of these factors within reasonable scientific bounds, but documentation to support their judgments must be clear and in the public record.

Maximum protection of human health from the potential effects of exposure to carcinogens through the consumption of contaminated fish and/or other aquatic life would require a criterion of zero. The zero level is based upon the assumption of non-threshold effects (*i.e.*, no safe level exists below which any increase in exposure does not result in an increased risk of cancer) for carcinogens. However, because a publicly acceptable policy for safety does not require the absence of all risk, a numerical estimate of pollutant concentration (in ug/l) which corresponds to a given level of risk for a population of a specified size is selected instead. A cancer risk level is defined as the number of new cancers that may result in a population of specified size due to an increase in exposure (*e.g.*, 10^{-6} risk level = 1 additional cancer in a population of 1 million). Cancer risk is calculated by multiplying the experimentally derived cancer potency estimate by the concentration of the chemical in the fish and the average daily human consumption of contaminated fish. The risk for a specified population (*e.g.*, 1 million people or 10^{-6}) is then calculated by dividing the risk level by the specific cancer risk. EPA's ambient water quality criteria documents provide risk levels ranging from 10^{-5} to 10^{-7} as examples.

The cancer potency estimate, or slope factor (formerly known as the q_1^*), is derived using animal studies. High-dose exposures are extrapolated to low-dose concentrations and adjusted to a lifetime exposure period through the use of a linearized multistage model. The model calculates the upper 95 percent confidence limit of the slope of a straight line which the model postulates to occur at low doses. When based on human (epidemiological) data, the slope factor is based on the observed increase in cancer risk and is not extrapolated. For deriving criteria for carcinogens, the oral cancer potency estimates or slope factors from IRIS are used.

It is important to note that cancer potency factors may overestimate or underestimate the actual risk. Such potency estimates are subject to great uncertainty because of two primary factors:

- adequacy of the cancer data base (*i.e.*, human vs. animal data); and
- limited information regarding the mechanism of cancer causation.

Risk levels of 10^{-5} , 10^{-6} , and 10^{-7} are often used by States as minimal risk levels in interpreting their standards. EPA considers risks to be additive, *i.e.*, the risk from individual chemicals is not necessarily the overall risk from exposure to water. For example, an individual risk level of 10^{-4} may yield a higher overall risk level if multiple carcinogenic chemicals are present.

For carcinogenic effects, the criterion can be determined by using the equation in [Exhibit 3-2](#).

If the receiving water body is not designated as a drinking water source, the factor WI can be deleted.

Exhibit 3-2. Equation for Deriving Human Health Criteria Based on Carcinogenic Effects

$$C \text{ (mg/l)} = \frac{(RL \times WT)}{q_1^* [WI + FC \times L \times (FM \times BCF)]}$$

where:

- C =
updated water quality criteria (mg/l)
- RL =
risk level (10^x) where x is usually in the range of 4 to 6
- WT =
weight of an average human adult (70 kg)
- q_1^* =
carcinogenic potency factor (kg day/mg)
- WI =
average human adult water intake (2 l/day)
- FC =
daily fish consumption (kg fish/day)

- $L =$
ratio of lipid fraction of fish tissue consumed to 3%
- $FM =$
food chain multiplier (from [Table 3-1](#))
- $BCF =$
bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/L water) for fish with 3% lipid content

Deriving Quantitative Risk Assessments in the Absence of IRIS Values

The RfDs or cancer potency estimates comprise the existing dose-response factors for developing criteria. When IRIS data are unavailable, quantitative risk level information may be developed according to a State's own procedures. Some States have established their own procedures whereby dose-response factors can be developed based upon extrapolation of acute and/or chronic animal data to concentrations of exposure protective of fish consumption by humans.

3.2 Relationship of Section 304(a) Criteria to State Designated Uses

The section 304(a)(1) criteria published by EPA from time to time can be used to support the designated uses found in State standards. The following sections briefly discuss the relationship between certain criteria and individual use classifications. Additional information on this subject also can be found in the "Green Book" (FWPCA, 1968); the "Blue Book" (NAUNAE, 1973); the "Red Book" (USEPA, 1976); the EPA *Water Quality Criteria Documents* (see [Appendix I](#)) (PDF) (5 pp, 224K); the "Gold Book" (USEPA, 1986a); and future EPA section 304(a)(1) water quality criteria publications.

Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use must be applied. The following four sections discuss the major types of use categories.

—3.2.1 Recreation

Recreational uses of water include activities such as swimming, wading, boating, and fishing. Often insufficient data exist on the human health effects of physical and chemical pollutants, including most toxics, to make a determination of criteria for recreational uses. However, as a general guideline, recreational waters that contain chemicals in concentrations toxic or otherwise harmful to man if ingested, or irritating to the skin or mucous membranes of the human body upon brief immersion, should be avoided. The section 304(a)(1) human health effects criteria based on direct human drinking water intake and fish consumption might provide useful guidance in these circumstances. Also, section 304(a)(1) criteria based on human health effects may be used to support this designated use where fishing is included in the State definition of "recreation." In this latter situation, only the portion of the criterion based on fish consumption should be used. Section 304(a)(1) criteria to protect recreational uses are also available for certain physical, microbiological, and narrative "free from" aesthetic criteria.

Research regarding bacteriological indicators has resulted in EPA recommending that States use *Escherichia coli* or enterococci as indicators of recreational water quality (USEPA, 1986b) rather than fecal coliform because of the better correlation with gastroenteritis in swimmers.

The "Green Book" and "Blue Book" provide additional information on protecting recreational uses such as pH criteria to prevent eye irritation and microbiological criteria based on aesthetic considerations.

—3.2.2 Aquatic Life

The section 304(a)(1) criteria for aquatic life can be used directly to support this designated use. If subcategories of this use are adopted (e.g., to differentiate between coldwater and warmwater fisheries), then appropriate criteria should be set to reflect the varying needs of such subcategories.

—3.2.3 Agricultural and Industrial Uses

The "Green Book" (FWPCA, 1968) and "Blue Book" (NASINAE, 1973) provide some information on protecting agricultural and industrial uses. Section 304(a)(1) criteria for protecting these uses have not been specifically developed for numerous parameters pertaining to these uses, including most toxics.

Where criteria have not been specifically developed for these uses, the criteria developed for human health and aquatic life are usually sufficiently stringent to protect these uses. States may also establish criteria specifically designed to protect these uses.

—3.2.4 Public Water Supply

The drinking water exposure component of the section 304(a)(1) criteria based on human health effects can apply directly to this use classification. The criteria also may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of contaminants in finished ("at-the-tap") drinking water.

A brief description of relevant sections of the SDWA is necessary to explain how the Act will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water. Pursuant to section 1412 of the SDWA, EPA has promulgated "[National Primary Drinking Water Standards](#)" for certain radionuclide, microbiological, organic, and inorganic substances. These standards establish maximum contaminant levels (MCLs), which specify the maximum permissible level of a contaminant in water that may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also treatment capability, monitoring availability, and costs. Under section 1401 (1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water that may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs, and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "at-the-tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria are more analogous to the maximum contaminant level goals (MCLGs) (previously known as RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allow an adequate margin of safety." MCLGs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the MCLGs.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment, ambient water criteria may be used by the States as a supplement to SDWA regulations. When setting water quality criteria for public water supplies, States have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria, or controls more stringent than these three to protect against the effects of contaminants by ingestion from drinking water.

For treated drinking water supplies serving 25 people or greater, States must control contaminants down to levels at least as stringent as MCLs (where they exist for the pollutants of concern) in the finished drinking water. However, States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment process reduces the level of pollutants, or a more stringent contaminant level than the former three options.

3.3 State Criteria Requirements

Section 131.11(a)(1) of the Regulation requires States to adopt water quality criteria to protect the designated use(s). The State criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use(s). For waters with multiple use designations, the criteria must support the most sensitive use.

In section 131.11, States are encouraged to adopt both numeric and narrative criteria. Aquatic life criteria should protect against both short-term (acute) and long-term (chronic) effects. Numeric criteria are particularly important where the cause of toxicity is known or for protection against pollutants with potential human health impacts or bioaccumulation potential. Numeric water quality criteria may also be the best way to address nonpoint source pollution problems. Narrative criteria can be the basis for limiting toxicity in waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity but where there are no numeric criteria in the State standards. Narrative criteria also can be used where toxicity cannot be traced to a particular pollutant.

Section 131.11(a)(2) requires States to develop implementation procedures which explain how the State will ensure that narrative toxics criteria are met.

To more fully protect aquatic habitats, it is EPA's policy that States fully integrate chemical-specific, whole-effluent, and biological assessment approaches in State water quality programs (see Appendix R). Specifically, each of these three methods can provide a valid assessment of *non-attainment* of designated aquatic life uses but can rarely demonstrate use *attainment* separately. Therefore, EPA supports a policy of independent application of these three water quality assessment approaches. Independent application means that the validity of the results of any one of the approaches does not depend on confirmation by one or both of the other methods. This policy is based on the unique attributes, limitations, and program applications of each of the three approaches. Each method alone can provide valid and independently sufficient evidence of non-attainment of water quality standards, irrespective of any evidence, or lack thereof, derived from the other two approaches. The failure of one method to confirm impacts identified by another method does not negate the results of the initial assessment.

It is also EPA's policy that States should designate aquatic life uses that appropriately address biological integrity and adopt biological criteria necessary to protect those uses (see section 3.5.3 and [Appendices C \(PDF\)](#) (60 pp, 4.5MB), [K \(PDF\)](#) (17 pp, 1.1MB), and [R \(PDF\)](#) (19 pp, 1.1MB)).

3.4 Criteria for Toxicants

Applicable requirements for State adoption of water quality criteria for toxicants vary depending upon the toxicant. The reason for this is that the 1983 Water Quality Standards Regulation ([Appendix A \(PDF\)](#) (27 pp, 2.3MB)) and the Water Quality Act of 1987 which amended the Clean Water Act (Public Law 100-4) include more specific requirements for the particular toxicants listed pursuant to CWA section 307(a). For regulatory purposes, EPA has translated the 65 compounds and families of compounds listed pursuant to section 307(a) into 126 more specific substances, which EPA refers to as "priority toxic pollutants." The 126 priority toxic pollutants are listed in the WQS regulation and in [Appendix P \(PDF\)](#) (4 pp, 150K) of this Handbook. Because of the more specific requirements for priority toxic pollutants* it is convenient to organize the requirements applicable to State adoption of criteria for toxicants into three categories:

- requirements applicable to priority toxic pollutants that have been the subject of CWA section 304(a)(1) criteria guidance (see section 3.4.1);
- requirements applicable to priority toxic pollutants that have not been the subject of CWA section 304(a)(1) criteria guidance (see section 3.4.1); and
- requirements applicable to all other toxicants (e.g., non-conventional pollutants like ammonia and chlorine) (see section 3.4.2).

—3.4.1 Priority Toxic Pollutant Criteria

The criteria requirements applicable to priority toxic pollutants (i.e., the first two categories above) are specified in CWA section 303(c)(2)(B). Section 303(c)(2)(B), as added by the Water Quality Act of 1987, provides that:

Whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection, or revises or adopts new standards pursuant to this paragraph 1 such State shall adopt criteria for all toxic pollutants listed pursuant to section 307(a)(1) of this Act for which criteria have been published under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses. Such criteria shall be specific numerical criteria for such toxic pollutants. Where such numerical criteria are not available, whenever a State reviews water quality standards pursuant to paragraph (1), or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria based on biological monitoring or assessment methods consistent with information published pursuant to section 304(a)(8). Nothing in this section shall be construed to limit or delay the use of effluent limitations or other permit conditions based on or involving biological monitoring or assessment methods or previously adopted numerical criteria.

EPA, in devising guidance for section 303(c)(2)(B), attempted to provide States with the maximum flexibility that complied with the express statutory language but also with the overriding congressional objective: prompt adoption and implementation of numeric toxics criteria. EPA believed that flexibility was important so that each State could comply with section 303(c)(2)(B) and to the extent possible, accommodate its existing water quality standards regulatory approach.

General Requirements

To carry out the requirements of section 303(c)(2)(B), whenever a State revises its water quality standards, it must review all available information and data to first determine whether the discharge or the presence of a toxic pollutant is interfering with or is likely to interfere with the attainment of the designated uses of any water body segment.

If the data indicate that it is reasonable to expect the toxic pollutant to interfere with the use, or it actually is interfering with the use, then the State must adopt a numeric limit for the specific pollutant. If a State is unsure whether a toxic pollutant is interfering with, or is likely to interfere with, the designated use and therefore is unsure that control of the pollutant is necessary to support the designated use, the State should undertake to develop sufficient information upon which to make such a determination. Presence of facilities that manufacture or use the section 307(a) toxic pollutants or other information indicating that such pollutants are discharged or will be discharged strongly suggests that such pollutants could be interfering with attaining designated uses. If a State expects the pollutant not to interfere with the designated use, then section 303(1)(2)(B) does not require a numeric standard for that pollutant.

Section 303(c)(2)(B) addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act, which are codified at 40 CFR 131.36(b). The section 307(a) list contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency has interpreted that list to include 126 "priority" toxic pollutants for regulatory purposes. Reference in this guidance to toxic pollutants or section 307(a) toxic pollutants refers to the 126 priority toxic pollutants unless otherwise noted. Both the list of priority toxic pollutants and recommended criteria levels are subject to change.

The national criteria recommendations published by EPA under section 304(a) (see section 3.1, above) of the Act include values for both acute and chronic aquatic life protection; only chronic criteria recommendations have been established to protect human health. To comply with the statute, a State needs to adopt aquatic life and human health criteria where necessary to support the appropriate designated uses. Criteria for the protection of human health are needed for water bodies designated for public water supply. When fish ingestion is considered an important activity, then the human health-related water quality criteria recommendation developed under section 304(a) of the CWA should be used; that is, the portion of the criteria recommendation based on fish consumption. For those pollutants designated as carcinogens, the recommendation for a human health criterion is generally more stringent than the aquatic life criterion for the same pollutant. In contrast, the aquatic life criteria recommendations for noncarcinogens are generally more stringent than the human health recommendations. When a State adopts a human health criterion for a carcinogen, the State needs to select a risk level. EPA has estimated risk levels of 10^{-5} , 10^{-6} , and 10^{-7} in its criteria documents under one set of exposure assumptions. However, the State is not limited to choosing among the risk levels published in the section 304(a) criteria documents, nor is the State limited to the base case exposure assumptions; it must choose the risk level for its conditions and explain its rationale.

EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations. However, if a State selects a criterion that represents an upper bound risk level less protective than 1 in 100,000 (e.g., 10^{-5}), the State needs to have substantial support in the record for this level. This support focuses on two distinct issues. First, the record must include documentation that the decision maker considered the public interest of the State in selecting the risk level, including documentation of public participation in the decision making process as required by the Water Quality Standards Regulation at 40 CFR 131.20(b). Second, the record must include an analysis showing that the risk level selected, when combined with other risk assessment variables, is a balanced and reasonable estimate of actual risk posed, based on the best and most representative information available. The importance of the estimated actual risk increases as the degree of conservatism in the selected risk level diminishes. EPA carefully evaluates all assumptions used by a State if the State chose to alter any one of the standard EPA assumption values (57 F.R. 60864, December 22, 1993).

EPA does not intend to propose changes to the current requirements regarding the bases on which a State can adopt numeric criteria (40 CFR 131.11(b)(1)). Under EPA's regulation, in addition to basing numeric criteria on EPA's section 304(a) criteria documents, States may also base numeric criteria on site-specific determinations or other scientifically defensible methods.

EPA expects each State to comply with the new statutory requirements in any section 303(c) water quality standards review initiated after enactment of the Water Quality Act of 1987. The structure of section 303(c) is to require States to review their water quality standards at least once each 3 year period. Section 303(c)(2)(B) instructs States to include reviews for toxics criteria whenever they initiate a triennial review. Therefore, even if a State has complied with section 303(c)(2)(B), the State must review its standards each triennium to ensure that section 303(c)(2)(B) requirements continue to be met, considering that EPA may have published additional section 304(a) criteria documents and that the State will have new information on existing water quality and on pollution sources.

It should be noted that nothing in the Act or in the Water Quality Standards Regulation restricts the right of a State to adopt numeric criteria for any pollutant not listed pursuant to section 307(a)(1), and that such criteria may be expressed as concentration limits for an individual pollutant or for a toxicity parameter itself as measured by whole-effluent toxicity testing. However, neither numeric toxic criteria nor whole-effluent toxicity should be used as a surrogate for, or to supersede the other.

State Options

States may meet the requirements of CWA section 303(c)(2)(B) by choosing one of three scientifically and technically sound options (or some combination thereof):

1. Adopt statewide numeric criteria in State water quality standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present;
2. Adopt specific numeric criteria in State water quality standards for section 307(a) toxic pollutants as necessary to support designated uses where such pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with designated uses;
3. Adopt a "translator procedure" to be applied to a narrative water quality standard provision that prohibits toxicity in receiving waters. Such a procedure is to be used by the State in calculating derived numeric criteria, which shall be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses.

Option 1 is consistent with State authority to establish water quality standards. Option 2 most directly reflects the CWA requirements and is the option recommended by EPA. Option 3, while meeting the requirements of the CWA, is best suited to supplement numeric criteria from option 1 or 2. The three options are discussed in more detail below.

Option 1

Adopt statewide numeric criteria in State water quality standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

Pro:

- simple, straightforward implementation
- ensures that States will satisfy statute
- makes maximum uses of EPA recommendations
- gets specific numbers into State water quality standards fast, at first

Con:

- some priority toxic pollutants may not be discharged in State
- may cause unnecessary monitoring by States
- might result in "paper standards"

Option 1 is within a State's legal authority under the CWA to adopt broad water quality standards. This option is the most comprehensive approach to satisfy the statutory requirements because it would include all of the priority toxic pollutants for which EPA has prepared section 304(a) criteria guidance for either or both aquatic life protection and human health protection. In addition to a simple adoption of EPA's section 304(a) guidance as standards, a State must select a risk level for those toxic pollutants which are carcinogens (*i.e.*, that cause or may cause cancer in humans).

Many States find this option attractive because it ensures comprehensive coverage of the priority toxic pollutants with scientifically defensible criteria without the need to conduct a resource-intensive evaluation of the particular segments and pollutants requiring criteria. This option also would not be more costly to dischargers than other options because permit limits would be based only on the regulation of the particular toxic pollutants in their discharges and not on the total listing in the water quality standards. Thus, actual permit limits should be the same under any of the options.

The State may also exercise its authority to use one or more of the techniques for adjusting water quality standards:

- establish or revise designated stream uses based on use attainability analyses (see section 2.9);
- develop site-specific criteria; or
- allow short-term variances (see section 5.3) when appropriate.

All three of these techniques may apply to standards developed under any of the three options discussed in this guidance. It is likely that States electing to use option 1 will rely more on variances because the other two options are implemented with more site-specific data being available. It should be noted, however, that permits issued pursuant to such water quality variances still must comply with any applicable antidegradation and antibacksliding requirements.

Option 2

Adopt specific numeric criteria in State water quality standards for section 307(a) toxic pollutants as necessary to support designated uses where such pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with designated uses.

Pro:

- directly reflects statutory requirement
- standards based on demonstrated need to control problem pollutants
- State can use EPA's section 304(a) national criteria recommendations or other scientifically acceptable alternative, including site-specific criteria
- State can consider current or potential toxic pollutant problems
- State can go beyond section 307(a) toxics list, as desired

Con:

- may be difficult and time consuming to determine if, and which, pollutants are interfering with the designated use
- adoption of standards can require lengthy debates on correct criteria limit to be included in standards
- successful State toxic control programs based on narrative criteria may be halted or slowed as the State applies its limited resources to developing numeric standards
- difficult to update criteria once adopted as part of standards
- to be absolutely technically defensible, may need site-specific criteria in many situations, leading to a large workload for regulatory agency

EPA recommends that a State use this option to meet the statutory requirement. It directly reflects all the Act's requirements and is flexible, resulting in adoption of numeric water quality standards as needed. To assure that the State is capable of dealing with new problems as they arise, EPA also recommends that States adopt a translator procedure the same as, or similar to, that described in option 3, but applicable to all chemicals causing toxicity and not just priority pollutants as is the case for option 3.

Beginning in 1988, EPA provided States with candidate lists of priority toxic pollutants and water bodies in support of CWA section 304(l) implementation. These lists were developed because States were required to evaluate existing and readily available water-related data to comply with section 304(l), 40 CFR 130.10(d). A similar "strawman" analysis of priority pollutants potentially requiring adoption of numeric criteria under section 303(c)(2)(B) was furnished to most States in September or October of 1990 for their use in ongoing and subsequent triennial reviews. The primary differences between the "strawman" analysis and the section 304(l) candidate lists were that the "strawman" analysis (1) organized the results by chemical rather than by water body, (2) included data for certain STORET monitoring stations that were not used in constructing the candidate lists, (3) included data from the Toxics Release Inventory database, and (4) did not include a number of data sources used in preparing the candidate lists (*e.g.*, those, such as fish kill information, that did not provide chemical-specific information).

EPA intends for States, at a minimum, to use the information gathered in support of section 304(l) requirements as a starting point for identifying (1) water segments that will need new and/or revised water quality standards for section 307(a) toxic pollutants, and (2) which priority toxic pollutants require adoption of numeric criteria. In the longer term, EPA expects similar determinations to occur during each triennial review of water quality standards as required by section 303(c).

In identifying the need for numeric criteria, EPA is encouraging States to use information and data such as:

- presence or potential construction of facilities that manufacture or use priority toxic pollutants;
- ambient water monitoring data, including those for sediment and aquatic life (e.g., fish tissue data);
- NPDES permit applications and permittee self-monitoring reports;
- effluent guideline development documents, many of which contain section 307(a)(1) priority pollutant scans;
- pesticide and herbicide application information and other records of pesticide or herbicide inventories;
- public water supply source monitoring data noting pollutants with Maximum Contaminant Levels (MCLs); and
- any other relevant information on toxic pollutants collected by Federal, State, interstate agencies, academic groups, or scientific organizations.

States are also expected to take into account newer information as it became available, such as information in annual reports from the Toxic Chemical Release Inventory requirements of the Emergency Planning and Community Right-To-Know Act of 1986 (Title III, Public Law 99-499).

Where the State's review indicates a reasonable expectation of a problem from the discharge or presence of toxic pollutants, the State should identify the pollutant(s) and the relevant segment(s). In making these determinations, States should use their own EPA-approved criteria or existing EPA water quality criteria for purposes of segment identification. After the review, the State may use other means to establish the final criterion as it revises its standards.

As with option 1, a State using option 2 must follow all its legal and administrative requirements for adoption of water quality standards. Since the resulting numeric criteria are part of a State's water quality standards, they are required to be submitted by the State to EPA for review and either approval or disapproval.

EPA believes this option offers the State optimum flexibility. For section 307(a) toxic pollutants adversely affecting designated uses, numeric criteria are available for permitting purposes. For other situations, the State has the option of defining site-specific criteria.

Option 3

Adopt a procedure to be applied to the narrative water quality standard provision that prohibits toxicity in receiving waters. Such a procedure would be used by a State in calculating derived numeric criteria to be used for all purposes of water quality criteria under section 303(c) of the CWA. At a minimum such criteria need to be derived for section 307(a) toxic pollutants where the discharge or presence of such pollutants in the affected waters could reasonably be expected to interfere with designated uses, as necessary to support such designated uses.

Pro:

- allows a State flexibility to control priority toxic pollutants
- reduces time and cost required to adopt specific numeric criteria as water quality standards regulations
- allows immediate use of latest scientific information available at the time a State needs to develop derived numeric criteria
- revisions and additions to derived numeric criteria can be made without need to revise State law
- State can deal more easily with a situation where it did not establish water quality standards for the section 307(a) toxic pollutants during the most recent triennial review
- State can address problems from non-section 307(a) toxic pollutants

Con:

- EPA is currently on notice that a derived numeric criterion may invite legal challenge
- once the necessary procedures are adopted to enhance legal defensibility (e.g., appropriate scientific methods and public participation and review), actual savings in time and costs may be less than expected
- public participation in development of derived numeric criteria may be limited when such criteria are not addressed in a hearing on water quality standards

EPA believes that adoption of a narrative standard along with a translator mechanism as part of a State's water quality standard satisfies the substantive requirements of the statute. These criteria are subject to all the State's legal and administrative requirements for adoption of standards plus review and either approval or disapproval by EPA, and result in the development of derived numeric criteria for specific section 307(a) toxic pollutants. They are also subject to an opportunity for public participation. Nevertheless, EPA believes the most appropriate use of option 3 is as a supplement to either option 1 or 2. Thus, a State would have formally adopted numeric criteria for toxic pollutants that occur frequently; that have general applicability statewide for inclusion in NPDES permits, total maximum daily loads, and waste load allocations; and that also would have a sound and predictable method to develop additional numeric criteria as needed. This combination of options provides a complete regulatory scheme.

Although the approach in option 3 is similar to that currently allowed in the Water Quality Standards Regulation (40 CFR 131.11(a)(2)), this guidance discusses several administrative and scientific requirements that EPA believes are necessary to comply with section 303(c)(2)(B).

1. The Option 3 Procedure Must Be Used To Calculate Derived Numeric Water Quality Criteria

States must adopt a specific procedure to be applied to a narrative water quality criterion. To satisfy section 303(c)(2)(B), this procedure shall be used by the State in calculating derived numeric criteria, which shall be used for all purposes under section 303(c) of the CWA. Such criteria need to be developed for section 307(a) toxic pollutants as necessary to support designated uses, where these pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with the designated uses.

To assure protection from short-term exposures, the State procedure should ensure development of derived numeric water quality criteria based on valid acute aquatic toxicity tests that are lethal to half the affected organisms (LC50) for the species representative of or similar to those found in the State. In addition, the State procedure should ensure development of derived numeric water quality criteria for protection from chronic exposure by using an appropriate safety factor applicable to this acute limit. If there are saltwater components to the State's aquatic resources, the State should establish appropriate derived numeric criteria for saltwater in addition to those for freshwater.

The State's documentation of the tests should include a detailed discussion of its quality control and quality assurance procedures. The State should also include a description (or reference existing technical agreements with EPA) of the procedure it will use to calculate derived acute and chronic numeric criteria from the test data, and how these derived criteria will be used as the basis for deriving appropriate TMDLs, WLAs, and NPDES permit limits.

As discussed above, the procedure for calculating derived numeric criteria needs to protect aquatic life from both acute and chronic exposure to specific chemicals. Chronic aquatic life criteria are to be met at the edge of the mixing zone. The acute criteria are to be met (1) at the end-of-pipe if mixing is not rapid and complete and a high rate diffuser is not present; or (2) after mixing if mixing is rapid and complete or a high rate diffuser is present. (See EPA's [Technical Support Document for Water Quality-based Toxics Control, USEPA 1991a \(PDF\)](#) (335 pp, 28.6MB))

EPA has not established a national policy specifying the point of application in the receiving water to be used with human health criteria. However, EPA has approved State standards that apply human health criteria for fish consumption at the mixing zone boundary and/or apply the criteria for drinking water consumption, at a minimum, at the point of use. EPA has also proposed more stringent requirements for the application of human health criteria for highly bioaccumulative pollutants in the [Water Quality Guidance for the Great Lakes System \(50 F. R. 20931, 21035, April 16, 1993\) \(PDF\)](#) (167 pp, 318K) including elimination of mixing zones.

In addition, the State should also include an indication of potential bioconcentration or bioaccumulation by providing for:

- laboratory tests that measure the steady-state bioconcentration rate achieved by a susceptible organism; and/or
- field data in which ambient concentrations and tissue loads are measured to give an appropriate factor.

In developing a procedure to be used in calculating derived numeric criteria for the protection of aquatic life, the State should consider the potential impact that bioconcentration has on aquatic and terrestrial food chains.

The State should also use the derived bioconcentration factor and food chain multiplier to calculate chronically protective numeric criteria for humans that consume aquatic organisms. In calculating this derived numeric criterion, the State should indicate data requirements to be met when dealing with either threshold (toxic) or non-threshold (carcinogenic) compounds. The State should describe the species and the minimum number of tests, which may generally be met by a single mammalian chronic test if it is of good quality and if the weight of evidence indicates that the results are reasonable. The State should provide the method to calculate a derived numeric criterion from the appropriate test result.

Both the threshold and non-threshold criteria for protecting human health should contain exposure assumptions, and the State procedure should be used to calculate derived numeric criteria that address the consumption of water, consumption of fish, and combined consumption of both water and fish. The State should provide the assumptions regarding the amount of fish and the quantity of water consumed per person per day, as well as the rationale used to select the assumptions. It needs to include the number of tests, the species necessary to establish a dose-response relationship, and the procedure to be used to calculate the derived numeric criteria. For non-threshold contaminants, the State should specify the model used to extrapolate to low dose and the risk level. It should also address incidental exposure from other water sources (e.g., swimming). When calculating derived numeric criteria for multiple exposure to pollutants, the State should consider additive effects, especially for carcinogenic substances, and should factor in the contribution to the daily intake of toxicants from other sources (e.g., food, air) when data are available.

2. The State Must Demonstrate That the Procedure Results in Derived Numeric Criteria Are Protective

The State needs to demonstrate that its procedures for developing criteria, including translator methods, yield fully protective criteria for human health and for aquatic life. EPA's review process will proceed according to EPA's regulation of 40 CFR 131.11, which requires that criteria be based on sound scientific rationale and be protective of all designated uses. EPA will use the expertise and experience it has gained in developing section 304(a) criteria for toxic pollutants by application of its own translator method (see Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Documents, USEPA, 1980b; [Guidelines for Deriving National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses USEPA, 1985b \(PDF\)](#) (11 pp, 1.5MB)).

Once EPA has approved the State's procedure, the Agency's review of derived numeric criteria, for example, for pollutants other than section 307(a) toxic pollutants resulting from the State's procedure, will focus on the adequacy of the data base rather than the calculation method. EPA also encourages States to apply such a procedure to calculate derived numeric criteria to be used as the basis for deriving permit limitations for nonconventional pollutants that also cause toxicity.

3. The State Must Provide Full Opportunity for Public Participation in Adoption of the Procedure

The Water Quality Standards Regulation requires States to hold public hearings to review and revise water quality standards in accordance with provisions of State law and EPA's Public Participation Regulation (40 CFR 25). Where a State plans to adopt a procedure to be applied to the narrative criterion, it must provide full opportunity for public participation in the development and adoption of the procedure as part of the State's water quality standards.

While it is not necessary for the State to adopt each derived numeric criterion into its water quality standards and submit it to EPA for review and approval, EPA is very concerned that all affected parties have adequate opportunity to participate in the development of a derived numeric criterion even though it is not being adopted directly as a water quality standard.

A State can satisfy the need to provide an opportunity for public participation in the development of derived numeric criteria in several ways, including:

- a specific hearing on the derived numeric criterion;
- the opportunity for a public hearing on an NPDES permits as long as public notice is given that a criterion for a toxic pollutant as part of the permit issuance is being contemplated; or
- a hearing coincidental with any other hearing as long as it is made clear that development of a specific criterion is also being undertaken.

For example, as States develop their lists and individual control strategies (ICSs) under section 304(1), they may seek full public participation. NPDES regulations also specify public participation requirements related to State permit issuance. Finally, States have public participation requirements associated with Water Quality Management Plan updates. States may take advantage of any of these public participation requirements to fulfill the requirement for public review of any resulting derived numeric criteria. In such cases, the State must give prior notice that development of such criteria is under consideration.

4. The Procedure Must Be Formally Adopted and Mandatory

Where a State elects to supplement its narrative criterion with an accompanying implementing procedure, it must formally adopt such a procedure as a part of its water quality standards. The procedure must be used by the State to calculate derived numeric criteria that will be used as the basis for all standards' purposes, including the following: developing TMDLs, WLAs, and limits in NPDES permits; determining whether water use designations are being met; and identifying potential nonpoint source pollution problems.

5. The Procedure Must Be Approved by EPA as Part of the State's Water Quality Standards Regulation